OCT 31 2000

K002546

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

(As required by 21 CFR 807.92)

CIV-Flex™ Holster Cover

A. General Information

Submitter's Name: CIVCO Medical Instruments Company, Inc.
Address: 102 First Street South, Kalona, IA 52247
Telephone No.: phone (319) 656-4447 fax: (877) 248-6304
Contact Person: J. William Jones, Manager - Regulatory Affairs

Date Prepared: 16 August 2000

Establishment Registration Number: 1937223
CIVCO Medical Instruments is registered as a medical device manufacturer.

Device Trade: **CIV-Flex™ Holster Cover**
Device Common: Biopsy Device Accessory
Device Classification Name: Biopsy Instrument Cover

Classification: Class II under 21 CFR 876.1075
Classification Panel: Gastroenterology
Classification Procode: 78 KNW

Performance Standards: No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.

B. Device Description

The **CIV-Flex™ Holster Cover** device provides a thin, conformal protective covering for the disposable probe / reusable holster and cable assembly components of the Ethicon Endo-Surgery Mammotome® mechanical breast biopsy device. The cover is manufactured as a one-piece sleeve design that is open on both ends with a tapered fit to the holster / probe geometry. The cover material is transparent for visualization of the holster control buttons during use.

Cover material is polyurethane film. Material system is free of any latex natural rubber. The polyurethane material was introduced into CIVCO products as CIV-Flex™ Ultrasound Transducer Covers in 1987. This polyurethane material has been used in CIVCO ultrasound transducer cover applications for over ten (10) years. Thus, this material can fall under a "GRAS" (Generally Recognized As Safe) classification.

Covers are packaged sterile in a pouch for single patient / procedure, disposable use. Cover is supplied with latex free Kraton® thermoplastic elastomer bands for use in securing the cover to the holster and cable.

C. Intended Use / Indications for Use

The **CIV-Flex™ Holster Cover** is a protective cover for a mechanical breast biopsy device reusable holster / cable assembly that helps prevent contamination [blood, body fluids, ultrasound gel, etc.] of the holster control buttons, and thus allowing for reprocessing of the holster between patient uses. Covers are single use, disposable.

D. Predicate Device

The CIV-Flex™ Holster Cover device is identified as substantially equivalent to CIVCO Medical's currently, legally marketed Poly [CIV-Flex™] Ultrasound Transducer Covers:

Predicate Device(s)	510(k) Reference	Manufacturer
Poly [CIV-Flex™] Ultrasound Transducer Cover	K970513	CIVCO Medical

E. Substantial Equivalence Summary

The **CIV-Flex™ Holster Cover** is substantially equivalent in safety and effectiveness to the CIVCO Poly [CIV-Flex™] Ultrasound Transducer Cover. The comparison table on the following pages demonstrates this substantial equivalence.

F. Conclusions

Ethicon Endo-Surgery User's Manual for the Mammotome® Hand-Held System indicates the holster / cable device is a non-sterile instrument and cannot be reprocessed between patient uses by chemical solution immersion methods. Reducing the contamination level by covering allows for reprocessing of the holster device by the instructed cleaning method of wiping with a cloth soaked with enzymatic detergent / removing residual detergent / drying. The open-ended sleeve type cover is not intended to be a sterile barrier. The holster is required to be cleaned after every use regardless of whether a sterile cover was used or not. Testing of the cover system has demonstrated satisfactory performance for contamination reduction.

This premarket submission for the **CIV-Flex™ Holster Cover** has demonstrated Substantial Equivalence as defined and understood in the Federal Food, Drug and Cosmetic act and various guidance documents issued by the Center for Devices and Radiological Health.

Comparison of Device to Substantially Equivalent, Legally Marketed Device

Parameter	CIV-Flex™ Holster Cover	***Predicate Device*** CIVCO Poly Ultrasound Transducer Cover (K970513)
Intended Use / Indications for Use	Same, except subject device is a mechanical breast biopsy reusable holster / cable assembly instead of an ultrasound transducer.	A protective cover that helps prevents contamination [blood, body fluids, ultrasound gel, etc.] and thus allowing for reprocessing of the device between patient uses. Covers are single use, disposable.
Design	Same.	One-piece, geometry conforming cover.
Material	Same.	▪ polyurethane, thermoplastic. ▪ CIVCO trade name *CIV-Flex™.* ▪ effectively used for over 10 years.
Manufacturing	Same.	▪ extruded / blown thin film sheet. ▪ cut / heat seal fabricated & packaged in a Class 10,000 cleanroom per Federal Std 209e. ▪ sterile packaging material system per ANSI / AAMI / ISO 11607. ▪ sterilized by ethylene oxide gas.
Quality Systems	Same.	▪ FDA/QSR cGMP 21CFR Part 820. ▪ ISO 9001 / EN46001 / ISO 13485.
Sterility	Same.	▪ sterilization by 100% EtO method. ▪ validated ANSI / AAMI / ISO 11135. ▪ SAL 10^{-6}.
Device Body Contact Category	Same.	▪ surface devices, intact skin / mucosal membranes / breached surfaces; limited contact duration (< 24 hours).

Comparison of Device to Substantially Equivalent, Legally Marketed Device cont.

Parameter	CIV-Flex™ Holster Cover	***Predicate Device*** CIVCO Poly Ultrasound Transducer Cover (K970513)
Safety	Same.	Biocompatibility tests for acute systemic toxicity, irritation, sensitization, hemolysis, material mediated pyrogen, and ethylene oxide sterilization residuals have demonstrated the polyurethane [CIV-Flex™] material / cover device is: ▪ non-toxic. ▪ non-sensitizing. ▪ non-irritating. ▪ non-hemolytic. ▪ non-pyrogenic. Testing is in accordance with - ISO 10993-Part 1 Biological Evaluation of Medical Devices, FDA Blue Book Memorandum #G95-1, and FDA-Good Laboratory Practices (GLP).
Effectiveness	Same. Mechanical testing for **CIV-Flex™ Holster Covers** has shown that the material is adequate for the intended use: a) during application and removal of cover from holster, b) during use as intended. ▪ Strength and elastic characteristics are the same as that of the ultrasound cover allowing use without tearing or pinholing. ▪ same cover thickness of .002".	Experience and testing has shown that polyurethane covers: ▪ polyurethane has sufficient strength and elasticity for the intended use. ▪ Nominal cover thickness is .002". ▪ Provides an effective barrier to the prevention of microbial migration as demonstrated using protocol adapted from that used to evaluate the barrier properties / resistance of surgical gloves and endoscope sheaths to penetration by bloodborne pathogens using viral penetration as a test method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Mr. J. William Jones
Regulatory Affairs Manager
CIVCO Medical Instruments Co, Inc.
102 First Street South
KALONA IA 52247-9589

Re: K002546
CIVCO Medical, CIV-Flex™ Holster Cover
Dated: August 16, 2000
Received: August 17, 2000
Regulatory Class: II
21 CFR §876.1075/Procode: 78 KNW

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into ~~either class~~ II (Special ~~Controls~~) or class III (Premarket ~~Approval~~), ~~it may be subject~~ to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation ~~may result in regulatory action~~. In addition, FDA may publish ~~further announcements~~ concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002546

Device Name: CIV-Flex™ Holster Cover

Indications For Use:

A protective cover for a mechanical breast biopsy device reusable holster / cable assembly that helps prevent contamination [blood, body fluids, ultrasound gel, etc.] of the holster control buttons, and thus allowing for reprocessing of the holster between patient uses; covers are single use, disposable.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002546